Claims PTO
2/6/04

AMENDMENTS TO THE CLAIMS

Applicants respectfully request the cancellation of Claim 58, for the reasons detailed below.

Claims 1-47 (previously cancelled).

Claim ~~48~~ 1 (previously presented): A method of screening for preneoplastic/neoplastic disease associated with abnormal MN gene expression comprising:

(a) determining whether abnormal MN gene expression is present in a vertebrate using a nucleic acid based assay on a sample from said vertebrate; and

(b) if abnormal MN gene expression is determined to be present in said vertebrate, determining that said vertebrate has a significant risk of having preneoplastic/neoplastic disease;

wherein said MN gene encodes an MN protein that is encoded by a nucleic acid having a nucleotide sequence selected from the group consisting of:

(1) SEQ ID NO: 1;

(2) nucleotide sequences that hybridize under stringent conditions to complement of SEQ ID NO: 1; and

(3) nucleotide sequences that differ from SEQ ID NO: 1 or from the nucleotide sequences of (b) in codon sequence due to the degeneracy of the genetic code.

Claim 49 (previously presented): The method of claim 48 wherein said MN protein is encoded by SEQ ID NO: 1.

Claim 50 (previously presented): The method of claim 49 wherein said vertebrate is a mammal.

Claim 51 (previously presented): The method of claim 49 wherein said vertebrate is a human.

Claim 52 (previously presented): The method of claim 51 wherein said nucleic acid based assay is a polymerase chain reaction based assay.

Claim 53 (previously presented): The method of claim 51 wherein detecting abnormal MN gene expression comprises:

(a) obtaining mRNA from said sample from said human; and

(b) detecting the presence of mRNA that is complementary to MN cDNA in the mRNA obtained from step (a), or

quantitating any mRNA that is complementary to MN cDNA in the mRNA obtained from step (a);

wherein the presence of mRNA complementary to MN cDNA in said mRNA obtained in step (a), or an abnormal level of mRNA complementary to MN cDNA in said mRNA obtained in step (a), indicates the presence of preneoplastic/neoplastic disease in said human.

Claim 54 (previously presented): The method of claim 51 wherein abnormal MN gene expression is detected by:

(a) obtaining mRNA from a sample from said human;

(b) preparing cDNA from the mRNA from step (a);

(c) amplifying any DNA encoding a MN protein or a MN polypeptide that is present in the cDNA prepared in step (b); and

(d) detecting the presence of any resulting amplified DNA, or quantitating any resulting amplified DNA, wherein the presence of such amplified DNA or an abnormal level of said amplified DNA indicates the presence of preneoplastic/neoplastic disease in said human.

Claim 55 (previously presented): The method of claim 54, wherein the step (c) amplification of DNA is effected by a

polymerase chain reaction utilizing at least two oligonucleotide primers.

Claim 56 (previously presented): The method of claim 55 wherein each of the primers is capable of specifically hybridizing with DNA that encodes MN protein.

Claim 57 (previously presented): The method of claim 56 wherein said DNA that encodes MN protein has the nucleotide sequence of SEQ ID NO: 1.

Claim 58 (canceled)

Claim 59 (previously presented): The method of claim 54, wherein the presence of any amplified DNA in step (d) is detected using a labeled MN nucleic acid probe which specifically hybridizes with any amplified MN DNA.

Claim 60 (previously presented): The method of claim 59, wherein the labeled probe is radiolabeled.

Claim 61 (previously presented): The method of claim 60 wherein the labeled probe is radiolabeled with ^{32}P.

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Claim 62 (previously presented): The method of claim 6 53 wherein said sample is selected from the group consisting of tissue sections, tissue extracts, tissue smears, whole cells, cell lysates, exfoliated cells, cell extracts, and body fluids.

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Claim 63 (previously presented): The method according 14 to claim 62 wherein said body fluid is selected from the group consisting of blood, serum, plasma, urine, semen, breast exudate, saliva, sputum, tears, mucous, fecal suspensions, gastric secretions, bile, lymph, cytosols, ascites, pleural effusions, amniotic fluid, bladder washes, bronchioalveolar lavages and cerebrospinal fluid.

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Claim 64 (previously presented): The method according 15 to claim 63 wherein said body fluid is selected from the group consisting of blood, serum and plasma.

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Claim 65 (previously presented): The method according 16 to claim 64 wherein said body fluid is blood.

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Claim 66 (previously presented): The method of claim 7 54 wherein said preneoplastic/neoplastic disease associated with abnormal MN gene expression is selected from the group consisting of mammary, urinary tract, bladder, kidney, ovarian,

uterine, cervical, endometrial, squamous cell, adenosquamous cell, vaginal, vulval, prostate, liver, lung, skin, thyroid, pancreatic, testicular, brain, head and neck, mesodermal, sarcomal, stomach, spleen, gastrointestinal, esophageal, and colon preneoplastic/neoplastic diseases.

Claim 67 (previously presented): The method of claim 66 wherein said neoplastic disease is renal carcinoma.

Claim 68 (previously presented): The method of claim 55 wherein each of said primers is an isolated and purified MN nucleic acid, which has a length of from 16 nucleotides to 50 nucleotides, and comprises a nucleotide sequence which is selected from the group consisting of: nucleotide sequences that specifically hybridize to SEQ ID NO: 1 or to the complement of SEQ ID NO: 1; and

wherein an appropriate pair of primers is selected for effective amplification.

Claim 69 (previously presented): The method of claim 68 wherein said nucleotide sequence specifically hybridizes to a MN nucleotide sequence contained in any of the plasmids A4a, XE1 and XE3, which were deposited at the American Type Culture

Collection in the United States of America under the respective ATCC Nos. 97199, 97200 and 97198.